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## The Use of Imiquimod for the Treatment of EMPD from the Patients' Perspective

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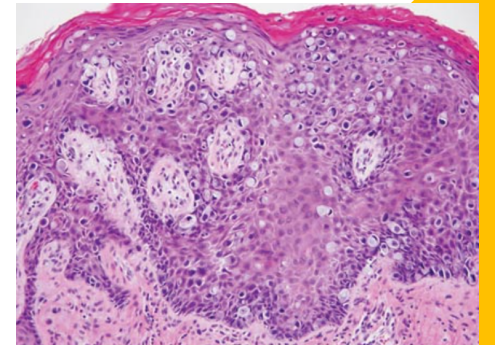
# Patient Experience with Imiquimod for Extramammary Paget's Disease

Darren D'Mello, Paul H. Chung, MD\*

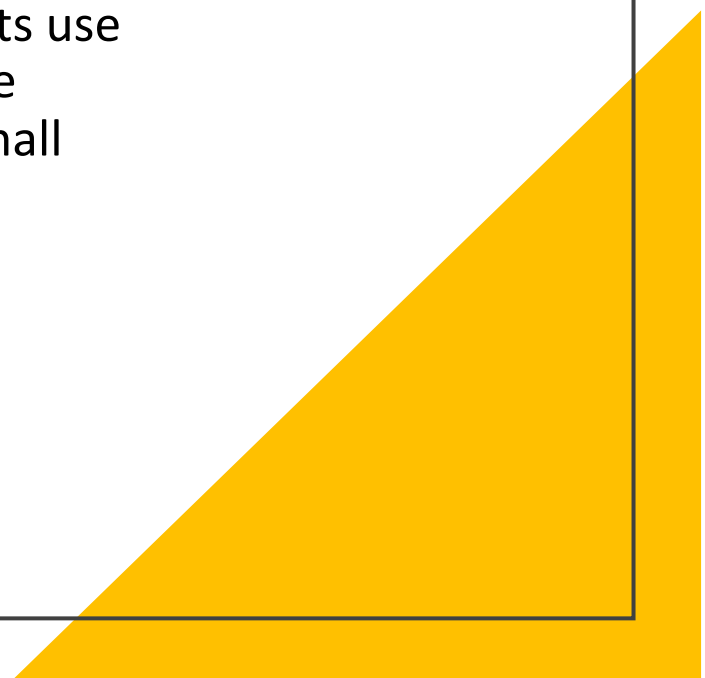


# Introduction

- Imiquimod is a topical medication that induces cytokines and modifies the innate immune response.
- It is used to treat many dermatologic conditions such as genital warts, superficial basal cell carcinoma, and actinic keratosis<sup>1</sup>. It has also been used to treat patients with Extra-Mammary Paget's Disease (EMPD).
- EMPD is a condition that presents as erythematous plaques that can progressively invade deep into the skin layers. It usually presents on the vulva, but perianal, penile, scrotal, and perineal skin are affected in some cases<sup>2</sup>.



# Cont.

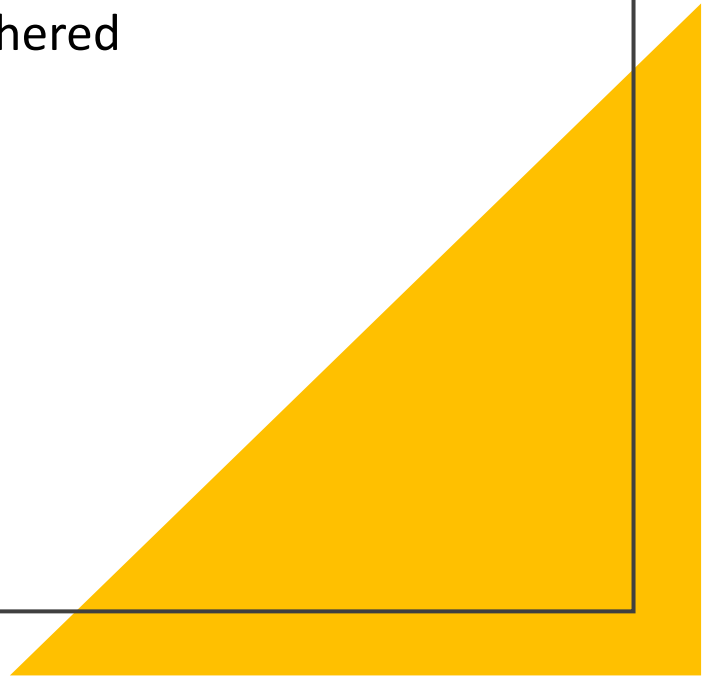
- Usually, EMPD is treated with surgery (skin graft, MMS) and sometimes with chemotherapy and other types of treatment. Imiquimod has been used in some cases but is being used more and more.
  - There have been case reports that described the effects and outcomes of patients who were treated with Imiquimod, but more research on its use for EMPD must be done. Much of these reports were created by the physicians reporting on their own patients, so sample sizes were small
  - There have been no studies that gathered data from the patients themselves; this is what our study hopes to accomplish.
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# Objectives and Hypothesis

- The purpose of the study is to gather information from patients who currently or previously had EMPD
- Some of the information that will be gathered includes:
  - Demographic information
  - Diagnostic information
    - When were they diagnosed, which kind of provider diagnosed them
  - Treatment information
    - Which treatments have they had, have they used imiquimod, side effects of the imiquimod, specific regimen used
  - Outcome information
    - What is the current status of the disease, was imiquimod effective by itself or with combination

# Objectives and Hypothesis

- We hypothesize that patients with EMPD who were treated with Imiquimod early after their diagnoses or after surgery had better outcomes than those who did not use Imiquimod at all.
- Our hypothesis may or may not be correct, but any information gathered will be novel and help further the information known about this treatment option for patients with EMPD



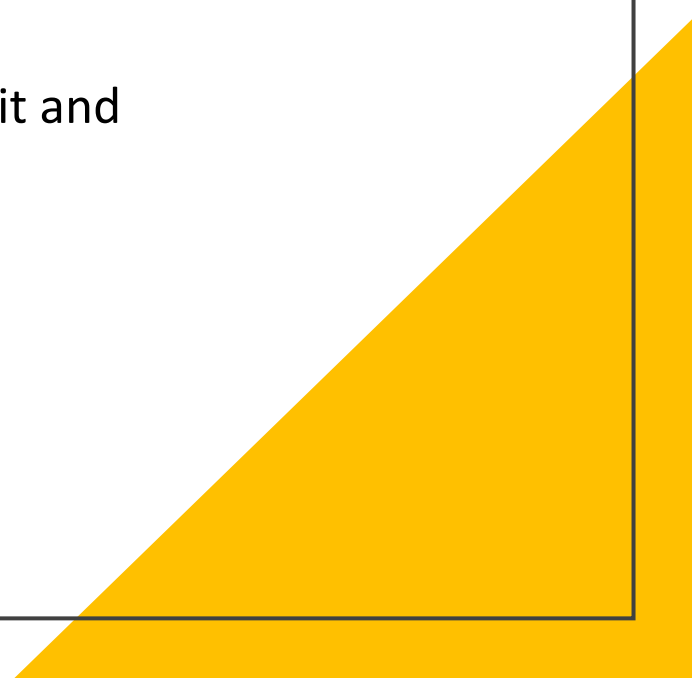
# Approach/Methods

- This study is a case series as we are asking patients who already have a particular disease to provide information
- Our patient pool is from a patient support group for EMPD
- A questionnaire made using Qualtrics will be sent to these patients
  - this questionnaire was created by us but was looked over by a dermatologist and an EMPD patient who is part of the support group in order to assess the relevance of the questions
- While data will come from the questionnaire, we also want to create a literature review of the many case reports of patients with EMPD treated with Imiquimod.
  - This involved the collecting all the papers reporting the use of the medicine in patients with the disease, and then formatting the information into a table that can be added into our paper

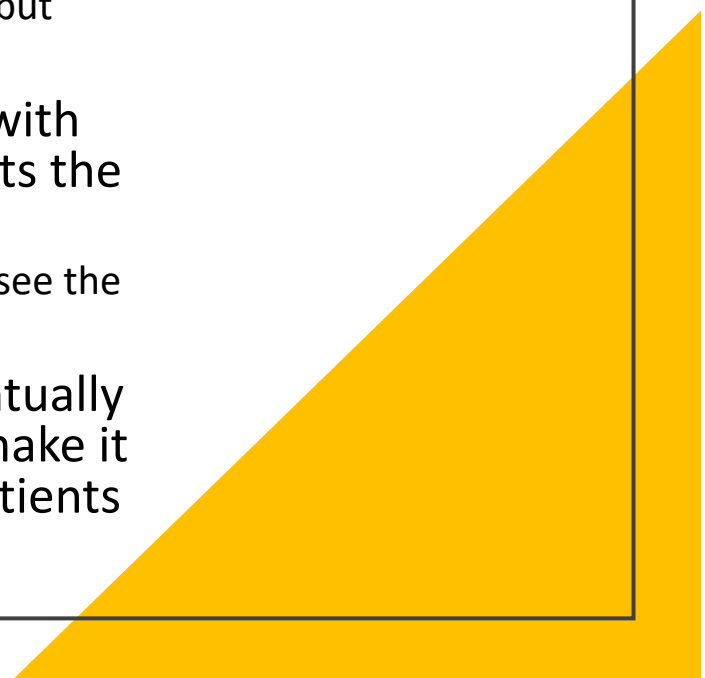
Paper	institution name	provider type	patient age	patient sex (f=m)	Chief complaint	location	diagnosis	medical history	procedure (0=no, 1=yes) and type	reoccurrence post surgery	Imiquimod use pre/post procedure
2002 zampogna (1st patient)	Division of dermatology	dermatology	57	1	4 yr hx of pruritic, erythematous lesions	right side of scrotum	primary limited cutaneous EMPD	NA	1, electrodesiccation and curettage	scar edges, 5.5x2.5cm	1
2002 zampogna (2nd patient)	division of dermatology	dermatology	72	1	10 yr hx of pruritic and erythematous lesions	perineal and left inguinal region	EMPD	hypertension, benign prostatic hyperplasia	0	NA	NA
2003 Berman, Spencer	university of miami	dermatology	68	1	indolent eczematous lesions	right groin, right scrotum	EMPD	NA	1, Mohs micrographic surgery	4 years later, right scrotum	1
2009 Challenor (case 1)	Departments of1General and 1Gynecology	OB/GYN	48	0	12 mo hx of vulval itching	NA	EMPD	NA	1, skinning vulvectomy and reconstruction	not all regions were removed	1, 6 weeks after surgery
2009 Challenor (case 2)	Departments of1General and 1Gynecology	OB/GYN	66	0	2 yr hx of vulval itching	NA	EMPD	NA	1, skinning vulvectomy and reconstruction	lateral margins were positive post op	1, 8 weeks post op
2016 Knight	Department of colorectal surgery	colorectal surge	40	0	2 yr hx of painful rash	perineal region	EMPD	erythema nodosum, perianal fissures	0	NA	NA
2014 Frances	Department of Dermatology	Dermatology	80	0	itching eczematous plaques	perineal region	EMPD	NA	1, radical vulvectomy	30 years later	1
2013 Toledo	Department of Dermatology	Dermatology	61	0	4 yr hx of pruritic lesions	perineum and genitals	primary limited EMPD	malignant tumor of groin	1, surgical excision	NA	0
2011 Matin	Centre for Cutaneous Medicine	NA	74	0	7-year history of a moist, erythematous plaque	vulva and perianal	EMPD	hypertension, hypercholesterolemia	1, surgical excision	NA	0
2003 Qian	Department of Dermatology	Dermatology	73	1	NA	Strotum and penis shaft	EMPD	NA	1, mohs micrographic surgery and reconstruction	Recurred many times over 6 years	1, after multiple surgery attempts
2003 wang	Section of Dermatology	Dermatology	75	0	1 yr, itching and burning	left upper vulva (labia majora)	EMPD	NA	1, surgical resection	1 year after	1
2006 badgwell	Department of Dermatology	dermatology	78	0	3 month hx of pruritic lesions	right upper inner thigh	EMPD	NA	0	NA	NA
2006 mirer (case 1)	Department of Dermatology	dermatology	80	0	5 month hx of asymptomatic lesions	anal margin, right major labia	EMPD	NA	0	NA	NA
2007 misery	Department of Dermatology	dermatology	74	0	7 yr empd	anal margin to the major labia	EMPD	NA	1, laser CO2	ineffective procedure so not cured	1
2007 vereecken	Departments of Dermatology	dermatology	66	1	perineal EMPD	perineal region	EMPD	NA	1, local resection 3 times in past 10 years	post resection sometime later	1
2008 Hatch (case 1)	University of Arizona	NA	68	0	6 yr hx of EMPD	vulva and perianal skin	EMPD	NA	1, resection	reacurrance after resection	1
2008 Hatch (case 2)	University of Arizona	NA	60	0	NA	vulva, groin, buttocks,	EMPD	NA	1, radical vulvectomy	2 yrs later	1, many years after reoccurrence
2009 yoo	Departments of Dermatology	dermatology	65	1	2-year history of a well-circumscribed, erythematous plaque	penile shaft	primary EMPD and Bowenoid papulosis	NA	0	NA	NA
2010 ho (case 1)	Division of Dermatology	dermatology	75	1	2 months rash	lower abdomen and external genitalia	EMPD	type II diabetes mellitus	0	NA	NA
2010 ho (case 2)	Division of Dermatology	dermatology	79	0	7 yr hx of rash	labia majora, the left thigh	EMPD	NA	0	NA	NA
2010 sendagorta (case 1)	Departments of Dermatology	dermatology	66	0	6 months pruritic lesions	vulvar area	EMPD	NA	0	NA	NA
2010 sendagorta (case 2)	Departments of Dermatology	dermatology	58	0	2 month burning sensation	left side vulva, inner thigh	EMPD	NA	0	NA	NA
2010 sendagorta (case 3)	Departments of Dermatology	dermatology	82	0	1 yr hx pruritic plaque	right labium majora	EMPD	NA	0	NA	NA
2011 anton	Obstetrics and Gynecology	OB/GYN	84	0	itching in pubic area	pubic area and left groin	EMPD	NA	0	NA	NA
2011 feldmeyer REVIEW	Department of Dermatology	dermatology	59	0	few months of sore at vulva	vulva, right labia majora	EMPD	NA	0	NA	NA
2011 gamero good discussion	?	dermatology	72	0	skin lesion with an erythematous plaque	vulva	EMPD	NA	0	NA	NA
2011 green REVIEW	Departments of Dermatology	dermatology	82	1	1 yr hx of pruritic lesions	suprapubic area, scrotum	EMPD	NA	1 excision of tumor	NA	0
2011 Hartman	Department of Dermatology	dermatology	60	1	genital eruption managed with topical steroids	lateral to right side of scrotum	EMPD	NA	1, Mohs micrographic surgery	margins still were positive for EMPD	1
2011 On (case 1)	Division of Dermatology	dermatology	75	1	1-year history of an erythematous plaque	right scrotum extending to perineum	EMPD	NA	1, radiation therapy	NA	0
2011 On (case 2)	Division of Dermatology	dermatology	70	1	4-year history of progressive pruritic scrotal dermatitis	scrotal	EMPD	BPH	1, radiation therapy	NA	0
2012 Herranz (3 patients)	Servicio de Dermatología	dermatology	66, 58, 82	0	vulvar lesions	vulvar regions for all 3	EMPD	"comorbid conditions"	0	NA	NA
2011 tonguc	Department of Oncology	oncology	65	0	2 yrs of itchy lesion on right labium	right labium extending to perineum	EMPD	NA	1, vulvar resection, then after resection	2 months after first surgery, 4 months after second	1



# Current and Future Plans

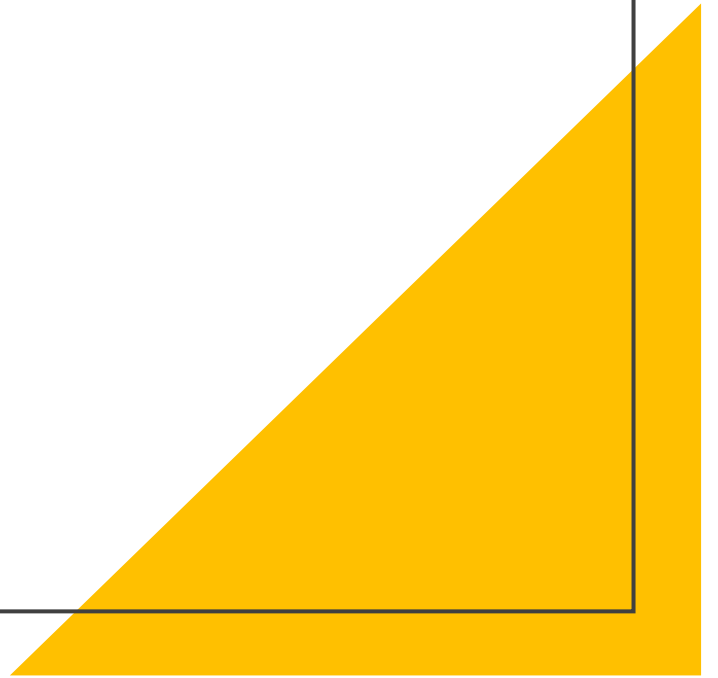
- As of now, I am completing the IRB forms necessary before sending out the questionnaire.
  - Once submitted, we are hoping to finish all edits on the questionnaire so that it can be sent out as soon as the IRB is approved.
  - Once we get the data from the questionnaire back, we will analyze it and look for any trends.
  - This data will be reported in our paper
  - Project should be complete around Fall this year.
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# Implications and Conclusion

- Considering how rare EMPD is, novel research on the disease and the treatments for it is not substantial
  - This is especially true of Imiquimod based treatment plans
    - The case reports that have been made about it have shown promising results, but samples are small
  - A study based on the patient's perspective of treatment for EMPD with Imiquimod would be a new way to look at how this treatment affects the patients when it comes to factors like efficacy, side effects, etc.
    - Including the review of the case reports will make it easy for future readers to see the other reports on the topic
  - Our hope is that future research builds upon our study so that eventually evidence-based guidelines on treating EMPD with Imiquimod will make it easier for physicians to treat patients and improve outcomes for patients
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# Acknowledgments

- I would like to thank:
  - Dr. Paul Chung who will continue to help guide me through the project
  - Dr. Elizabeth Jones who helped revise the questionnaire
  - Mr. Steve Schroeder who helped revise the questionnaire



# Citations

- <sup>1</sup> Vidal, D., 2021. *Topical Imiquimod: Mechanism of Action and Clinical Applications*.
- <sup>2</sup> McDaniel, B., Brown, F. and Crane, J., 2021. *Extramammary Paget Disease*. [online] Ncbi.nlm.nih.gov. Available at: <<https://www.ncbi.nlm.nih.gov/books/NBK493224/>> [Accessed 2 February 2021].
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